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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,310	05/18/2007	Nicholas Outram	10400C-000250/US	8148
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EXAMINER				
PORTER, JR, GARY A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/590,310

Applicant(s)

OUTRAM ET AL.

Examiner

GARY A. PORTER, JR

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 18, 20 and 21 is/are rejected.
- 7) ☒ Claim(s) 12-17 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-10, 20 and 21 rejected under 35 U.S.C. 102(b) as being anticipated by Porges (US Patent 4,510,944) (cited in the last Office Action).

3. Regarding Claim 1, Porges teaches a sensor 1 for detecting bioelectric potentials, specifically in regards to fetal heart rate (col. 4, lines 38-68; col. 6, lines 55-68). Porges further teaches that the system detects a primary fetal heart rate component and then subtracts the primary fetal heart rate component from the determined fetal heart rate in order to determine a residual component (col. 6, line 64 – col. 8, line 13; col. 9, lines 55-67). The residual component is then used to provide an accurate estimate of the variances associated with heart period rhythms (col. 7, lines 65-67). Porges also teaches that the primary fetal heart rate component is identified through a polynomial curve fit approximation, wherein the fetal heart rate data is divided into periods of time, i.e. time windows, and individual polynomial approximations are

performed for each period that are combined to represent a smooth approximation for the aperiodic trend(col. 6, line 64 - col. 7, line 13; col. 8, lines 23-27; col. 9, lines 55-67).

4. In regards to Claim 2, Porges discloses after the "outliner compensator" conditions the signal, the fetal heart rate data is resampled at a rate that is twice the frequency of interest and then a polynomial curve fit approximation is performed (col. 7, line 41 - col. 9, line 68).

5. With regards to Claims 3-5, Porges teaches that it is preferable to use a third order polynomial (col. 9, lines 50-52). However, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Porges specifically teaches that higher order polynomials can be used (Claim 4; col. 10, line 63 - col. 11, line 5) therefore giving the system the capability of using a 5th or 12th order polynomial without changing the structure of the invention (*specifically the circuitry in Fig. 2a of Porges*).

6. Regarding Claim 6, Porges teaches that the polynomial approximation is a least squares approximation (col. 10, lines 39-41).

7. In regards to Claim 7, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed

invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In this case, Porges teaches that the fetal heart rate data is divided into 500 msec time windows (col. 8, lines 23-28; col. 9, lines 53-55) and then passed to the moving polynomial filter where they are trended (col. 10, lines 1-19). The result of the approximation is shown in Fig. 3. Since the graph is a continuous curve, it can be assumed that the approximations of the time windows align. The system as disclosed by Porges is therefore capable of performing the same function as described by Applicant.

8. With regards to Claims 8 and 9, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In his case, the system of Porges is capable of setting the time windows so that 20 consecutive heart samples can be obtained, since Porges explicitly states that as long as the sampling rate is twice the

frequency of interest, any sampling rate can be chosen (col. 8, lines 20-57) thus any window of data can be set.

9. Regarding Claim 10, Porges teaches statistical analysis of the residual component, i.e. the variability of the heart rate, is used to determine various distress states of a fetus (col. 14, lines 11-66).

10. In regards to Claim 20, Porges teaches a sensor 1 for detecting bioelectric potentials, specifically in regards to fetal hear rate (col. 4, lines 38-68; col. 6, lines 55-68). Porges further teaches that a primary fetal heart rate component is identified and then subtracted from the determined fetal heart rate in order to determine a residual component (col. 6, line 64 – col. 8, line 13). The residual component is then used to provide an accurate estimate of the variances associated with heart period rhythms (col. 7, lines 65-67).). Porges also teaches that the primary fetal heart rate component is identified through a polynomial curve fit approximation, wherein the fetal heart rate data is divided into periods of time, i.e. time windows, and individual polynomial approximations are performed for each period that are combined to represent a smooth approximation for the aperiodic trend (col. 6, line 64 - col. 7, line 13; col. 8, lines 23-27; col. 9, lines 55-67).

11. With regards to Claim 21, Porges teaches a computer readable medium with instructions on it that perform the approximations (col. 11, lines 1-48) as addressed in the rejection of Claims 1 and 20.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porges (US Patent 4,510,944) in view of Ferguson, II et al. (US Pub. 2006/0074329). Porges discloses performing statistical comparisons of the residual components to a control group and concluding the health of the fetus from the comparison. Porges also discloses circuitry that performs the statistical computations (*specifically variance calculations display 96, results are also evident in Fig. 4a and 4b*) in order to predict fetal distress (col. 2, lines 14-23; col. 5, lines 1-44). Porges does not disclose that distribution analysis of the 95th percentile of the fetal heart rate residual component is performed to predict fetus well-being. However, Ferguson teaches using quantitative distribution analysis to predict fetal well-being and fetal outcome (Section [0011, 0018]; Fig. 7-9). Additionally, Ferguson teaches that percentiles of interest are

evaluated, i.e. 90th percentile (Section [0068]), and used in statistical models (Section [0071]) to predict fetal condition (Section [0063]). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Porges reference to include using distribution statistical analysis based on percentiles, as taught and suggested by Ferguson, for the purpose of predicting fetal abnormalities. This combination meets the claim limitations since the structure of the combination is the same as set forth in Applicant's claims. The system of the Porges and Ferguson combination is certainly capable of determining the condition of a fetus using the 95th percentile since it can determine the condition of a fetus using the 90th percentile.

Allowable Subject Matter

14. Claims 12-17 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: The current state of the art, as indicated by Porges and Ferguson, teaches that polynomial curve fitting is well known in fetal heart rate monitoring. Specifically, as taught by Porges, using the polynomial curve fit approximations, primary fetal heart rate components and residual components of the heart signal can be obtained. Furthermore, Ferguson illustrates that statistical analysis is prevalent when interpreting

these heart components, specifically statistical analysis involving percentile values of the signal.

16. Where Applicant's invention differs from the prior art is the processing step of taking a median and a variance of the 95th percentile of the residual component. The Examiner was unable to find a teaching in the prior art that discloses such a processing step.

Response to Arguments

17. Applicant's arguments with regards to Claims 1 and 20 filed 5/7/2009 have been fully considered but they are not persuasive.

18. Applicant argues at pages 12 and 13 "that Porges does not disclose 'performing individual polynomial curve fit approximations of the fetal heart rate development over time data for each period of time, each of the individual polynomial curve fit approximations resulting in a polynomial curve' or 'assembling the polynomial curves to form the primary fetal heart rate component.'" The Examiner respectfully disagrees.

19. Porges teaches performing polynomial curve fit approximations on individual time windows (col. 8, lines 23-57; col. 9, lines 61-63), therefore reading on the claim limitation "performing individual polynomial curve fit approximations of the fetal heart rate development over time data for each period of time." The period of time Porges describes is 500 msec.

20. Porges further teaches that the polynomial curve approximations for each time window result in a contiguous, "smooth" curve that represents the entire aperiodic trend

(Fig. 1b; col. 6, line 64- col. 7, line 5; col. 9, lines 55-67). Since this curve is representative of the polynomial approximations of the individual time windows, this curve is an "assembly" of the individual polynomial approximations.

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art
Unit 3766